

EPA's DfE Standard for Safer Cleaning Products (SSCP)

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Foreword

EPA Design for the Environment (DfE) Program

DfE partners to advance environmental protection. The Design for the Environment (DfE) Program is one of the U.S. Environmental Protection Agency's (EPA's) most valued partnership programs. The DfE Program works in partnership with a broad range of stakeholders to reduce risk to people and the environment by preventing pollution. DfE focuses on industries that combine the potential for chemical risk reduction and improvements in energy efficiency with a strong motivation to make lasting, positive changes. DfE convenes partners, including industry representatives and environmental groups, to develop goals and guide the work of the partnership. Partnership projects evaluate human health and environmental characteristics, performance, and cost of traditional and alternative technologies, materials, and processes. As incentives for participation and driving change, DfE offers unique technical tools, methodologies, expertise, and the potential for product recognition.

DfE enables the selection of safer alternatives through informed substitution. Located in the Office of Pollution Prevention and Toxics, the DfE Program promotes safer product design and green chemistry alternatives through "informed substitution," the considered transition from a chemical of particular concern to safer chemicals or non-chemical alternatives. The goals of informed substitution are to minimize the likelihood of unintended consequences, which can result from a precautionary switch away from a chemical of concern without fully understanding the profile of potential alternatives, and to enable a course of action based on the best information—on the environment and human health—that is available or can be estimated. To be considered safer choices, potential alternatives should exhibit as many of the following characteristics as possible: they should be technically feasible; deliver the same or better value in cost and performance; provide an improved profile for health and the environment; account for economic and social considerations; and have the potential to result in lasting change.

DfE's Formulator Program

DfE applies informed substitution to cleaning products. The DfE Program applies informed substitution to critical areas of environmental and human health protection. In the cleaning industry, the DfE Program partners with product manufacturers, or "formulators," environmentalists, and others, exchanging information and collaborating on the development of safer products. Formulators have been invaluable in helping DfE understand the critical elements of product functionality and how to optimize product and health/environmental performance. Environmentalists have provided important insight on chemical characteristics, especially for defining the green end of the health/environmental spectrum, as well as identifying ways to ensure confidence in partnership environmental results.

To inform substitution, DfE considers each ingredient in a product within its distinct functional class (e.g., surfactants, solvents, chelating agents, etc.) and compares the toxicity and fate profiles to identify the safest ingredients. DfE recognition is based on using the safest possible ingredients to make a high-performing, cost-effective product. DfE considers whole product characteristics, like possible negative synergies between ingredients and pH level, as well as lifecycle factors, like energy efficiency and water savings.

DfE's functional class approach screens for safer ingredients. Each ingredient in a formulation has a role to play in making a product work. Whether it is to aid in cleaning by reducing surface tension (surfactants), dissolve or suspend materials (solvents), reduce water hardness (chelating agents), or provide a scent (fragrances), each ingredient type has a function. Within these "functional classes," many ingredients share similar toxicological and environmental fate characteristics. As a result, DfE focuses its review of formulation ingredients on the key environmental and human health characteristics of concern within a functional class. This approach allows formulators to use those ingredients with the lowest hazard in their functional class, while still formulating high-performing products.

DfE uses the technical expertise of its workgroup of EPA scientists to compare ingredients in the same functional class and thereby identify those ingredients with the lowest hazard profile. The program is now developing *DfE Standards* for safer chemical ingredients to share this expertise and make it easier to formulate safer products. These Standards are used to identify safer chemical ingredients, particularly for use in cleaning products.

A DfE-labeled product contains the safest possible ingredients. The DfE label offers a readily identifiable way to know that a product is as safe as possible for people and the environment. When you see the DfE label on a product it means that the DfE scientific review team has screened each ingredient for potential human health and environmental effects and that—based on the best available experimental data and EPA predictive models—the product contains only those ingredients that pose the least concern among chemicals in their class. For example, if a DfE-recognized product contains a surfactant, then that surfactant will not be toxic to humans and it will biodegrade readily to non-polluting degradation products. Many surfactants in conventional products biodegrade slowly or biodegrade to more toxic and persistent chemicals, which threaten aquatic life.

Product formulators who become DfE partners, and earn the right to display the DfE label on recognized products, have invested heavily in research, development, and reformulation to ensure that their ingredients and finished product align at the green end of the health and environmental spectrum, while maintaining or improving product performance.

DfE uses a rigorous, in-depth approach to review products. By focusing at the ingredient level and on inherent characteristics, DfE is able to carefully scrutinize formulations and make meaningful calls on potential concerns. DfE starts its product reviews with information that scientists already know about each chemical ingredient, such as how it works in a product and how it affects living things. When that information doesn't tell the full story, EPA looks at an ingredient's chemical structure—its components and shape—to understand how it could impact the environment and people.

A chemical's structure can tell a lot about how the chemical will behave and what types of effects it may have when it comes in contact with people or the environment. DfE uses the special skills of the scientists at EPA who are experts in chemical analysis, hazard and risk assessment, and green chemistry.

DfE review is especially discriminating and protective. The DfE Program is unique because of two defining characteristics: its assessment methodology and its technical review team. The DfE technical review team has many years of experience and is highly skilled at assessing chemical hazards, applying predictive tools, and identifying safer substitutes for chemicals of concern. The review team applies the DfE assessment methodology by carefully reviewing every product ingredient. (The review includes all chemicals, including those in proprietary raw material blends, which supplier companies share with DfE in confidentiality).

DfE reviews provide an extra measure of protection. DfE uncovers chemicals of concern that can be masked by raw material blends or by dilution in water. By focusing at the ingredient level and on inherent characteristics, DfE is able to carefully scrutinize formulations and make meaningful calls on potential concerns. For example, a surfactant that is acutely toxic to aquatic organisms and environmentally persistent can appear to pose a low concern when blended with other less toxic and less persistent surfactants. Similarly, water, typically the largest percentage ingredient even in concentrated products, can mask the toxicity of a hazardous chemical.

DfE uses its expert knowledge and predictive tools to supplement lists of chemicals of concern. Few chemicals in commerce have been completely characterized, especially for chronic effects like cancer and developmental toxicity. For this reason, lists of chemicals with these effects can

only be considered works in progress. DfE uses its knowledge of the structural similarities between chemicals and its predictive models to flag ingredients with similar potential effects.

DfE spots negative synergies between product components. These potentially dangerous chemical combinations, which occur with surprising frequency in cleaning products, pose concerns for both acute and longer-term effects. For example, mixing nitro-containing compounds with amines will create nitrosamines, potent carcinogens.

DfE screens all ingredients for chemicals that may present serious health or environmental effects. This screening includes ingredients used in small percentages, like fragrances and dyes. Some of the chemicals of most potential concern in cleaning products are those used in small concentrations. Chemicals of concern include sensitizers, carcinogens, and environmentally toxic and persistent compounds. Small quantities don't necessarily mean small hazards: a person, once sensitized to a chemical, can have an allergic response even if exposed at minute levels.

DfE recommends safer substitutes for chemicals of concern. Movement toward sustainability requires innovation and continuous improvement. The DfE program works directly with EPA's green chemistry specialists to identify and recommend safer chemicals to its partners, continuously raising the bar and redefining the meaning of environmentally preferable products. DfE helps partners by sharing information and guiding the development of safer products. This is a win for industry, families, and the environment.

DfE Criteria for Cleaning Products

1 Purpose, Scope, and Normative References

1.1 Purpose

This document, the Design for the Environment (“DfE”) Criteria for Cleaning Products (the “DfE Criteria”), establishes minimum requirements for identifying cleaning products that meet the U.S. Environmental Protection Agency’s DfE Safer Product Labeling Program (also known as the Formulator Program) criteria.

1.2 Scope

The DfE Criteria are intended to cover cleaning products including but not limited to, glass cleaners, general purpose cleaners, washroom cleaners, carpet cleaners, floor care products, laundry detergents, graffiti removers, marine cleaning products, and drain cleaners. While this document includes the review criteria for both the whole product and each product component, the DfE recognition applies only to the finished cleaning product.

1.3 Normative References

The following documents are referenced in this text.

AATCC Test Method 171-1995.

ASTM D4488 –95(2001)e1 Standard Guide for Testing Cleaning Performance of Products Intended for Use on Resilient Flooring and Washable Walls.

ASTM D5343 – 06 Standard Guide for Evaluating Cleaning Performance of Ceramic Tile Cleaners.

ASTM D6094 – 97 Standard Guide to Assess the Compostability of Environmentally Degradable Nonwoven Fabrics.

ASTM G122 – 96(2002) Standard Test Method for Evaluating the Effectiveness of Cleaning Agents.

California’s Proposition 65 – Safe Drinking Water and Toxic Enforcement Act of 1986.

CSPA DCC-03 – Performance Test Methods and Guidelines – Rug Shampoo.

CSPA DCC-09 – Performance Test Methods and Guidelines – Glass Cleaners.

CSPA DCC-09A – Performance Test Methods and Guidelines – Standard Guide for Evaluating the Filming and Streaking of Glass Cleaners.

CSPA DCC-10 – Performance Test Methods and Guidelines – Foam Stability of Hand Dishwashing Detergents.

CSPA DCC-11 – Performance Test Methods and Guidelines – Home Laundering Pre-Wash Spotter Stain Removal.

CSPA DCC-12 – Performance Test Methods and Guidelines – Guidelines for Screening the Efficacy of Oven Cleaners.

CSPA DCC-13 – Performance Test Methods and Guidelines – Fabric Softeners.

CSPA DCC-14 – Guidelines for Anti-Redeposition Properties of Laundry Products.

CSPA DCC-16 – Guidelines for Evaluating the Efficacy of Bathroom Cleaners.

CSPA DCC-17 – Greasy Soil Test Method for Evaluating Spray-and-Wipe Cleaners Used on Hard, Non-Glossy Surfaces.

CAN/CGSB 2-GP-11, Method 20.3.

DfE Master Criteria for Safer Ingredients – See
<http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Master>

DfE Criteria for Surfactants – <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Surfactants>

DfE Criteria for Solvents -- <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#SolventsPhaseI>

DfE Criteria for Chelating and Sequestering Agents –
<http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Chelating>

DfE Criteria for Environmental Toxicity and Fate for Chemicals in Direct Release Products –
<http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Toxicity>

DfE Criteria for Fragrances – <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Fragrances>

DfE Partnership Agreement – Annex A.

Globally Harmonized System of Classification and Labeling of Chemicals (GHS)
http://www.unece.org/trans/danger/publi/ghs/ghs_rev02/02files_e.html.

2 Reference Section

2.1 Definitions

Terms used in the DfE Criteria document that have a specific technical meaning are defined here.

2.1.1 Absorbent: A material with the tendency to take up another substance into the bulk of the material.

2.1.2 Adsorbent: A substance that attracts other substances to its surface, often for odor control purposes.

2.1.3 Allergen: An antigenic substance capable of producing immediate-type hypersensitivity. (See also skin and respiratory sensitizer)

2.1.4 Amine: An organic compound containing a basic (alkaline) nitrogen atom. Amines may be primary (R-NH₂), secondary (R₂NH) or tertiary (R₃N).

2.1.5 Analog: Closely-related chemical structures. (Reference: Analog Information Model)

2.1.6 Antifoamer: A material that prevents or minimizes the formation of foam.

2.1.7 Antioxidant: A chemical compound or substance that inhibits oxidation.

2.1.8 Antiredeposition agent: An ingredient used in detergents to help prevent loosened soil from resettling after it has been removed during washing.

2.1.9 Association of Occupational and Environmental Clinics (AOEC) list of occupational asthma-gens: A list of respiratory sensitizers and irritants found in occupational settings. For more information, please see <http://www.aoec.org/>.

2.1.10 Asthma: A chronic disorder of the airways that is complex and characterized by variable and recurring symptoms, airflow obstruction, bronchial hyperresponsiveness (bronchospasm), and an underlying inflammation. Asthma symptoms may be induced by a sensitizer (allergen) or an irritant.

2.1.11 Asthmagen: An agent that causes asthma.

2.1.12 Bacteria, spore: A refractile body formed within bacteria, especially genera of the family Bacillaceae, which is regarded as a resting stage during the life history of the cell, and is characterized by its resistance to environmental changes.

2.1.13 Bacteria, vegetative: Single-celled organisms belonging to kingdom Monera that possess a prokaryotic type of cell structure, which means their cells are non-compartmentalized, and their DNA is found throughout the cytoplasm rather than within a membrane-bound nucleus. Vegetative bacteria are in growth phase or reproductive phase; nutrients are not limited and the bacteria are not in spore form.

2.1.14 Bioaccumulation: The progressive increase in the amount of a substance in an organism or part of an organism, which occurs because the rate of intake exceeds the organism's ability to remove the substance from the body.

2.1.15 Biodegradability: The capability of organic matter to be decomposed by biological processes. Both the rate and the completeness of decomposition are factors in biodegradability.

2.1.16 Bleaching agent: A chemical that acts by oxidizing stains to break them down and remove color.

2.1.17 Builder: A broad category of materials that enhance or maintain the cleaning efficiency of the surfactant. Several types of compounds, with different performance capabilities, are used. Builders have a number of functions, principally to inactivate water hardness and to supply alkalinity. This is accomplished either by sequestration (i.e. holding hardness minerals in solution, by precipitation, or by ion exchange). Other functions of builders are to supply alkalinity to assist cleaning, especially of acid soils, to provide buffering so that alkalinity is maintained at an effective level, to aid in keeping removed soil from re-depositing during washing. Builders for the purposes of this document include chelators, alkalinity boosters, pH adjusters, and buffering agents.

2.1.18 California Proposition 65: A California law that regulates substances the state lists as causing cancer, birth defects, or other reproductive harm. For more information, see <http://www.oehha.org/prop65.html>

2.1.19 Chelating agent: An organic chemical that forms two or more coordination bonds with a central metal ion. Heterocyclic rings are formed with the central metal ion as part of each ring. Chelating agents can change the properties of metal ions, help to transport metal ions, and prevent scale formation.

2.1.20 Coalescing agent: A chemical that lowers the minimum film formation temperature of a polymer (typically in a floor finish) so that it will form a uniform film at normal indoor temperatures. These chemicals are typically solvents.

2.1.21 Colorant: Any substance, natural or synthetic, whose primary use is to color various materials.

2.1.22 Component: A chemical as identified by its Chemical Abstract Service (CAS) number.

2.1.23 Compostable: Capable of undergoing biological decomposition in a compost site as part of an available program, such that the material is not visually distinguishable and breaks down into carbon dioxide, water, inorganic compounds, and biomass, at a rate consistent with known compostable materials.

2.1.24 Corrosion inhibitor: A substance that prevents the disintegration of a material into its constituent atoms.

2.1.25 Cross-linker: A material that forms covalent bonds between polymer chains, either within or across chains.

2.1.26 Defoamer: Agent used to reduce foam.

2.1.27 Denaturation: 1. A process that renders a substance unfit to eat or drink without destroying its usefulness in other applications, for example adding methanol or a bittering agent to ethyl alcohol. 2. A change in molecular structure of proteins so that they cannot function normally, often caused by splitting of hydrogen bonds following exposure to reactive substances or heat.

2.1.28 Direct release products: Products that are intended for use in applications that result in their immediate release to the environment, so that they bypass sewage treatment or septic systems, shortening the time for degradation prior to entering sensitive environments. Home car washes, boat cleaners and graffiti removers are examples of direct-release products.

2.1.29 Dispersing agent: A material that increases the stability of particles in a liquid formulation.

2.1.30 Endocrine disruption list: **European Commission** list of substances prioritized for testing for endocrine disruption as identified in the June 2000 BKH report, "*Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*" and its subsequent revisions.

2.1.31 Enzyme: A protein that acts as a catalyst in biochemical reactions. Each enzyme is specific to a particular reaction or group of similar reactions.

2.1.32 Enzyme stabilizer: A chemical that maintains the activity of enzymes in the formulation by preventing degradation and denaturation prior to use.

2.1.33 Foam booster: An additive used in detergents to increase suds production and stabilize lather.

2.1.34 Formulator: A company that designs and makes chemical choices for the manufacture of products. DfE partners with formulator companies. Formulators may private label or license their DfE-recognized formulas and thereby extend DfE recognition to their licensees or private label customers. Key in DfE's decision to extend recognition to private label or licensed products is a demonstration that the partner retains full control of the recognized formulation.

2.1.35 Fluorescent whitening agent: (optical brightener) Complex, organic molecules that adhere to fabrics as though they were dyes. Ultraviolet (UV) energy is absorbed, converted, and emitted as visible blue light to enhance fabric appearance and maintain whiteness or brightness.

2.1.36 Fluorosurfactant: Any organic substance which contains fluorine-based functional groups and has surface-active properties.

2.1.37 Fragrance: A raw material or a mixture of fragrance raw materials for use in a cleaning product for the primary purpose of imparting a scent and/or masking base odor.

2.1.38 Fragrance raw material: Any basic substance, obtained by chemical synthesis or derived from a natural source, present in a fragrance at greater than 0.01 percent by weight. Fragrance raw materials include aroma chemicals, fragrant extracts (essential oils), and all auxiliary materials, including--but not limited to - solvents, surfactants/solubilizers, UV inhibitors, antioxidants, stabilizers, preservatives, and fixatives.

2.1.39 Hydrotrope: A substance that increases the solubility in water of another material, which is only partially soluble.

2.1.40 Ingredient: One component or a blend of components that are intentionally added to make up a finished product. All ingredients are subject to this standard, regardless of percentage in the formulation. See Section 5.13 for information on residuals.

2.1.41 Irritant: An agent that induces inflammation. Respiratory irritants may produce Reactive Airway Dysfunction Syndrome (RADS), also called irritant induced asthma.

2.1.42 Licensee product: A product whose contents are identical to those in a DfE-recognized product that is manufactured by a third-party, non-DfE partner under a contract between the DfE-partner/manufacturer and the third party/licensee.

2.1.43 Manufacturer: A company that manufactures a finished product formulation. DfE may partner with product manufacturers.

2.1.44 Mesophilic: A descriptive term for a phase in the composting process that occurs between temperatures of 20 to 45°C (68 to 113°F) and is characterized by the presence and activity of organisms capable of thriving at these temperatures.

2.1.45 Optical brightener: An alternate name for fluorescent whitening agent. (FWA]

2.1.46 Persistence: The length of time the chemical can exist in the environment before being destroyed (i.e., transformed) by natural processes.

2.1.47 pH adjuster: Acids or bases that decrease or increase pH as needed in a formula.

2.1.48 Photosensitizer: A chemical which causes a photoallergy. Photoallergy is a form of allergic reaction due to a metabolite formed by the influence of light. The second and subsequent exposures produce photoallergic skin conditions, which are often eczematous.

2.1.49 Plasticizer: Plasticizers are additives that give hard plastics the desired flexibility, durability or other functional characteristics.

2.1.50 Polymer: A chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight.

2.1.51 Preservative: A substance that protects against the natural effects of aging, such as decay, discoloration, oxidation, and bacterial degradation.

2.1.52 Private label product: A product whose contents are identical to those in a DfE-recognized product, or vary only as to minor components (reviewed by DfE and specified in the Partnership Agreement), that is manufactured by a DfE partner for a third-party/private-label company or distributor.

2.1.53 Protease: An enzyme, also called a peptidase, which catalyzes the cleavage of internal peptide bonds in a polypeptide or protein.

2.1.54 Residual: Trace amounts of chemicals that are incidental to manufacturing. Residuals are not part of the intended chemical product, but are present because of factors such as the nature of the synthesis and engineering pathways used to produce the chemical. Residuals include: unintended by-products of chemical reactions that occur in product formulation and chemical synthesis, impurities in an ingredient that may arise from starting materials, incompletely reacted components, and degradation products.

2.1.55 Residual of concern: A residual that fails to meet the criteria in the General Standard for carcinogenicity, mutagenicity, reproductive toxicity and other human health effects, or fails to meet the criteria for persistence, bioaccumulation and toxicity, as defined by the Final PB&T Rule. See Section 5.13 for more information.

2.1.56 Rheology modifier: A chemical that modifies the viscosity of a formulation.

2.1.57 Sensitization: The progressive amplification of a response following repeated administrations of a stimulus.

2.1.58 Sensitizer, respiratory: A substance that will lead to hypersensitivity of the airways and resultant effects following inhalation.

2.1.59 Sensitizer, skin: A substance that will induce an allergic response following skin contact.

2.1.60 Solubility enhancer: A chemical additive that prevents chemicals or materials from separating or falling out of solution. Solubility enhancers are often used in concentrated formulations. Solubility enhancers consist of subcategories such as hydrotropes and small amines.

2.1.61 Solvent: A liquid that has the ability to dissolve, suspend, or extract other materials without causing chemical change to the material or solution.

2.1.62 Supplier: A manufacturer of a chemical component or ingredient, which is not an end-use product. A supplier furnishes raw materials to formulators.

2.1.63 Surfactant: Any organic substance and/or preparation which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces. Surfactants may also be used for purposes other than detergents such as emulsifiers, foaming agents, wetting agents, and stabilizers for dispersions.

2.1.64 Terpenes: Unsaturated hydrocarbons occurring in most essential oils and oleoresins of plants. Their structures are based on isoprene units, and may be cyclic or linear.

2.1.65 Toll manufacture product: A product whose contents are identical to those in a DfE-recognized product that is manufactured by a third-party, non-DfE partner under an agreement between the DfE partner and the third-party/toll manufacturer.

2.1.66 Vapor: The gaseous form of a substance or mixture released from its liquid or solid state.

2.2 Abbreviations

AATCC – American Association of Textile Chemists and Colorists

ANSI – American National Standards Institute

AOEC – Association of Occupational and Environmental Clinics

ASTM – American Society for Testing and Materials

CAS – Chemical Abstract Service

CSPA – Consumer Specialty Products Association

DfE – Design for the Environment

DOT – Department of Transportation

EPA – US Environmental Protection Agency

FDA – Food and Drug Administration

FIFRA – Federal Insecticide, Fungicide, Rodenticide Act

GHS – Globally Harmonized System of Classification and Labeling of Chemicals

HAP – Hazardous Air Pollutant

IARC – International Agency for Research on Cancer
ISO – International Standards Organization
IUPAC – International Union of Pure and Applied Chemistry
MSDS – Material Safety Data Sheet
NTP – National Toxicology Program
OECD – Organisation for Economic Co-operation and Development
OSHA – Occupational Health and Safety Administration
PBT – Persistent, Bioaccumulative and Toxic
SIDS – Screening Information Data Set
TRI – Toxic Release Inventory
TSCA – Toxic Substances Control Act
VOC – Volatile Organic Compound

3 General Requirements

3.1 General

3.1.1 Product and material information described in Section 3.2 shall be used to determine the specific section under which a product and its ingredients shall be evaluated.

3.1.2 Products or ingredients whose intended uses fall under more than one section of the DfE Criteria document shall be evaluated under the section having the most rigorous evaluation criteria.

3.1.3 To obtain DfE recognition for a product, the applicant must comply with the information requirements in Section 3.2 et seq. and must enter into a Partnership Agreement with EPA. The Partnership Agreement governs the relationship between EPA/DfE and its partner, the product formulator or manufacturer. It contains, among other elements, provisions covering the following: full ingredient disclosure; notification of changes in formula and the need for prior DfE approval; the partner's commitment to continuous product improvement; limitations and responsibilities regarding use of the DfE recognition and logo; and partnership sunset and opportunity for renewal. A sample Partnership Agreement, containing all required elements, appears in Annex A.

3.2 Information and Formulation Requirements

3.2.1 The applicant shall submit, at a minimum, the complete product formulation information. All ingredients shall be reviewed to ensure that the potential environmental and human health effects of products and ingredients are accurately and adequately identified. Applicants must report all ingredients intentionally added to the formulation, regardless of percentage. Known residuals must be reported if present at greater than 0.01 percent by weight; see the discussion of residuals in Section 5.13. Applicants must report:

- The intended function or end use of the product or the material;
- The composition of the formulation, including the percent or percent range of each ingredient in the formulation and its corresponding function;
- A Chemical Abstract Service (CAS) number, functional name, trade designation, and supplier for each chemical present in the formulation;
- A Material Safety Data Sheet (MSDS) for the product and each ingredient, when available;
- The pH of the finished product, if applicable;
- Effective use concentrations;

- The expected yearly production volume of the end-use product;
- Product performance data (see Section 4.2.1);
- Information on environmental considerations in packaging (see Section 4.2.6);
- When available, a list of published and unpublished toxicological studies relevant to the chemicals and impurities present in the product, component, or material; and
- Any other available supplemental product or ingredient environmental health and safety information, including biodegradation tests on individual ingredients; acute aquatic toxicity tests on product as a whole or individual ingredients; and human health and safety tests.

3.2.2 By reviewing the formulation information provided by the applicant, DfE or its designate will determine any formulation-dependent contaminants to be evaluated in addition to the product-specific analytes identified in each product section.

3.3 Renewals

As described in Section A.15 of the Partnership Agreement, DfE partners must renegotiate and renew the partnership prior to its expiration date (i.e., three years from the date of initiation). As part of the renegotiation, DfE will consider the partner's performance under the partnership, including, but not limited to, its achievement of any continuous improvement targets specified in the agreement. Discussion of green chemistry innovations and opportunities for formulation improvements will be part of the renegotiations.

3.4 End-User Education

Formulators of DfE-recognized products shall provide their end-user(s) with information on environmental, consumer, and worker safety matters. DfE encourages partners to provide customers with a 16-section format MSDS as established by the American National Standards Institute (ANSI) standard for preparation of MSDSs (Z400.1). The partner or its distributor shall offer training on the proper use of the product (instructions on how to dilute, use and dispose of the product). OSHA, DOT, and other authorities require manufacturers to provide handling and other worker safety information.

3.5 Compliance

As described in Section A.10 of the Partnership Agreement, partners agree to make available to the EPA/DfE, on a confidential basis, formulation bills of material (e.g., batch tickets) to confirm that the recognized products contain the ingredients as described in the Partnership Agreement.

3.6 Verification of Partnership Compliance

3.6.1 Annual desk audit

DfE partners will submit to the third-party verifier specified materials (elements of the desk audit are listed in Annex B.1). These materials will include a list of ingredients for each recognized product and a statement that the ingredients and all claims made regarding the Agency's recognition (e.g. use of the DfE logo) comport with the Partnership Agreement.

3.6.2 On-site audit

DfE partners will allow the third-party verifier to visit their manufacturing facilities and conduct audits (elements of the on-site audit are listed in Annex B.2). The audit will focus on the manufacturing process and the procedures in place to ensure that recognized products comport with the Partnership Agreement.

If a single facility produces a recognized product, that facility will be subject to a site audit once per three-year partnership period. If multiple facilities produce a recognized product, two sites will be selected for an audit once per three-year partnership period. Licensees and toll manufacturers are subject to the same rules as primary partners and their facilities will be considered separately from the facilities of the primary partner.

3.6.3 External verifier

An external verifier—a person or body carrying out the verification—will conduct the site visits or paper audits. The external verifier must meet the criteria for qualified third parties in Section 7 of this document, as well as the competencies for external verifiers for products in ISO/IEC Guide 65: General criteria for bodies operating product certification systems. Competence criteria are specified in Sections 5.1.1, 5.1.2 and 5.2.1. An external verifier must be free of any potential conflicts of interest.

3.6.4 Results

If the audit reveals items of noncompliance, the partner must promptly correct the noncompliance. The noncompliant company must submit to the external verifier and to DfE, in writing and within 30 days of receiving written notice of noncompliance, the following: a root-cause analysis, an explanation of corrective action, and a preventive action plan. In collaboration with DfE, the external verifier must confirm that the partner has taken the remedial action necessary to assure DfE of the partner's ability to satisfy the terms of the Partnership Agreement. Unaddressed or egregious noncompliance may serve as grounds for terminating the partnership. In any case of serious noncompliance, the DfE partner may be asked to immediately cease use of the DfE logo; procedures for handling existing stocks of products and labels will be determined on a case-by-case basis. The noncompliant partner must provide written confirmation that they have ceased using the DfE logo and an estimate of the quantities of the currently labeled product(s).

3.7 Third-Party Manufacture of DfE-labeled Products

3.7.1 Private label products

A private label product may carry the DfE logo provided that its contents are either identical to those in a specified DfE-recognized product, or very similar, and the ingredients that are different have been approved in the Partnership Agreement. Before manufacture of the private label product that will carry DfE recognition, the DfE partner must inform and receive permission from DfE, indicating the name of the private label product, the label owner, and the specific DfE-recognized product to which it is identical or on which it is based. Private label products are subject to the audit provisions contained in Section 3.6.

3.7.2 Licensee products

A licensee product may carry the DfE logo provided that its contents are identical to those in a specified DfE-recognized product. Before manufacture of the licensee product, the DfE partner must inform and receive permission from DfE, indicating the name of the licensee manufacturer and of the specific DfE-recognized product to which the licensee product is identical. To assure quality, the licensee product must be manufactured under an agreement between the DfE partner and the licensee and the agreement must be available to DfE on request. DfE partners must ensure that their licensees submit to the audit provisions contained in Section 3.6.

3.7.3 Toll-manufactured products

A toll manufacture product may carry the DfE logo provided that its contents are identical to those in a specified DfE-recognized product. Before toll manufacture of the DfE-recognized product, the DfE partner must inform and receive permission from DfE, indicating the name of the toll manufacturer and of the specific DfE-recognized product to which the toll-manufactured product is identical. To assure quality and compliance with the Partnership Agreement, the toll-manufactured product must be manufactured under an agreement between the DfE partner and the toll manufacturer and the agreement must be available to DfE on request. DfE partners must ensure that their toll manufacturers submit to the audit provisions contained in Section 3.6.

3.8 Ingredient Communication

To enhance public awareness of the safer ingredients in DfE-recognized cleaning products and in the spirit of more complete communications on chemicals in common use, formulator-partners must disclose the contents of their DfE-recognized products as described herein.

3.8.1 Scope

Except as provided below, manufacturers must publicly disclose all intentionally added ingredients in their DfE-labeled products, except for “incidental ingredients,” that is, ingredients present at insignificant levels that have no technical or functional effect (e.g., reagents, processing aids, and impurities, as defined in 21 CFR §701.3(l)).

3.8.2 Locus of disclosure

Ingredients must be disclosed in one of the following locations: on the product label; on the formulator’s Web site; at a toll-free number; or, on another media approved by DfE. If disclosure does not occur on the product label, the formulator must provide the location of the ingredients on the label, e.g., the Web site address or toll-free number.

3.8.3 Ingredient descriptions

Except for ingredients protected as trade secrets (as defined in the Uniform Trade Secrets Act), formulators must use the Chemical Abstract Service (CAS) number, if available, and one or more of the following nomenclature systems to describe their ingredients: CAS name; Consumer Specialty Products Association (CSPA) Consumer Products Ingredient Dictionary name; International Nomenclature of Cosmetic Ingredients (INCI) name; or, International Union of Pure and Applied Chemistry (IUPAC) name.

Generally, for ingredients protected as trade secrets, a manufacturer may use a chemical-descriptive name, for example, the EPA Premanufacture Notice generic name or the CSPA Dictionary name, in lieu of the specific chemical name; however, the name must be as specific as possible without revealing trade secret information. (A determination by the formulator that an ingredient is a trade secret for the purposes of public disclosure does not affect how the DfE program handles potentially trade secret information in its possession. The DfE program handles information claimed by program participants as confidential business information in accordance with the Agency confidentiality procedures found at 40 CFR Part 2, Subpart B.)

The following categories of ingredients are commonly protected as trade secrets. When ingredients in these categories are trade secrets, they should be disclosed as follows:

Dyes and colorants. Dyes and colorants should be listed by a chemical-descriptive name.

Fragrances. Scent ingredients may be listed as “Fragrance,” on the label, but the formulator must indicate where detailed information can be found; for example, the Web site list, or subset of

the list, of fragrance materials authored by the International Fragrance Association (IFRA) and available on IFRA's Web site (<http://www.ifraorg.org/>). Alternatively, if not a matter of trade secrets, the product formulator may state on its Web site the palette of fragrance materials used in its products or the ingredients in the fragrance, and may include, at the formulator's discretion, ingredients not used in the fragrance.

Preservatives. Preservatives in non-pesticidal products should be listed by a chemical-descriptive name. Pesticidal preservatives are subject to the US EPA Office of Pesticide Program regulations and guidance.

3.8.4 Listing Order

Formulators must use the following approach in listing ingredients: for those present at concentrations over 1.0 percent (measured on a weight-weight percentage basis), ingredients must be listed in descending order, with the ingredient at the highest percentage in formula listed first; for those present at or below 1.0 percent, ingredients may be listed in any order.

4 Product-Level Requirements

4.1 Scope

The requirements in this section apply to finished cleaning products, including those in the following categories: all-purpose, hard surface, glass, degreasers, Kitchen and bath, hand dish, drain cleaning and maintenance, floor care, carpet care, car care, laundry, dish detergents, marine cleaning, graffiti removal, and odor removal.

4.2 Criteria for All Products

4.2.1 Performance

To ensure a baseline measure of performance, the applicant must make a good faith demonstration that their products perform effectively. Applicants must submit appropriate test results as specified below or provide equivalent performance tests agreed upon by DfE.

Performance testing requirements are product-category specific. Partners and candidate partners must consult DfE or an authorized third-party profiler concerning product categories not specifically addressed below. Each product shall effectively clean common soils and surfaces in its category at the most diluted/least concentrated manufacturer-recommended dilution level for routine cleaning, as measured by the following applicable standard test methods.

Manufacturers may use an alternative method approved by DfE to test performance. The alternative method must be objective and scientifically validated, conducted under controlled and reproducible laboratory conditions. For consumer products, the product must perform similar to a conventional, nationally recognized product in its category and at equivalent product-specific use directions. For non-consumer products, DfE must approve the acceptable performance level. Test methodology and results must be documented in sufficient detail for this determination to be made.

Examples of performance requirements that are acceptable to DfE include but are not limited to:

4.2.1.1 Glass cleaners

The product must achieve at least a rating of three for cleaning, streaking and smearing when tested according to CSPA method DCC-09 and DCC-09A or equivalent method agreed upon by DfE.

4.2.1.2 All-purpose cleaners

The product must remove at least 80% of the particulate or greasy soils, as appropriate, when tested according to ASTM G122, DCC-17, CAN/CGSB 2-GP-11 Method 20.3 or an equivalent method agreed upon by DfE.

4.2.1.2 Carpet cleaners/spot cleaners

The product must meet user requirements when tested according to CSPA DCC-03 and AATCC Test Method 171-1995. Alternatively, the product may be tested for cleaning efficacy and resoiling resistance using another equivalent method agreed upon by DfE as described in Section 4.2.1. Products that have WoolSafe certification or a Carpet and Rug Institute Cleaning Solutions Seal of Approval, or the equivalent, will be deemed to satisfy this provision.

4.2.1.4 Washroom cleaners

The product must remove at least 75% of soil using ASTM D5343-06, CSPA DCC-16 or equivalent method agreed upon by DfE. If the product is used for toilet bowl or urinal cleaning, it must also demonstrate efficacy under diverse water hardness conditions using an appropriate method agreed upon by DfE, as described in Section 4.2.1.

4.2.1.5 Degreasers

The product must meet user requirements for soil removal on relevant substrates when tested according to ASTM method G122, CAN/CGSB 2-GP-11, Method 20.3, CSPA DCC-17 or an equivalent method agreed upon by DfE.

4.2.1.6 Laundry and related products

A consumer pre-wash spotter stain remover must meet user requirements in CSPA DCC-11 or an equivalent method agreed upon by DfE.

A fabric softener must meet user requirements in CSPA DCC-13 or an equivalent method agreed upon by DfE.

A laundry detergent must meet user requirements in CSPA DCC-14 or an equivalent method agreed upon by DfE.

4.2.1.7 Oven cleaners

An oven cleaner must meet user requirements in CSPA DCC-12 or an equivalent method agreed upon by DfE.

4.2.1.8 Hand dish soaps

A hand dish soap must meet user requirements in CSPA DCC-10 or an equivalent method agreed upon by DfE.

4.2.2 pH

To minimize potential for dermal and eye irritation or injury, product pH must be ≥ 2 and ≤ 11.5 . Products with $\text{pH} < 2$ or > 11.5 may be considered for recognition if *in vivo* assays prove the product is not corrosive to the skin or to the eyes.

4.2.3 Life-cycle considerations

4.2.3.1 Energy

DfE encourages the use of energy-saving technologies including the use of concentrates and detergents that work in cold water. DfE considers energy efficiency by comparing product efficiency to that typical of the class, recognizing the importance of reducing energy use and generation of greenhouse gases. DfE expects that energy-efficient products would continue to meet the hazard criteria in Section 5.

4.2.3.2 Ozone depleting compounds

DfE-recognized products must not contain ozone-depleting compounds as defined by the 1987 Montreal Protocol. (<http://www.epa.gov/ozone/science/ods/index.html>)

4.2.5 Labeling requirements

The DfE partner must provide its customers with information on environmental, consumer, and worker safety matters. The DfE partner must also meet OSHA, DOT, and any other authority's requirements to provide safe handling and other worker safety information, as applicable.

4.2.6 Packaging

DfE requires partners to implement sustainable packaging measures and to improve the packaging profile for their recognized products during the partnership. To qualify as a partner, a company must be at least at a 25 percent level with regard to its labeled products in one of the six sustainability criteria listed below, developed by the Sustainable Packaging Coalition (<http://www.sustainablepackaging.org>). For example, to meet the minimum initial DfE packaging requirement, a qualifying partner must be using 25 percent renewable or recycled source materials in its primary packaging. (This provision pertains to the primary packaging, i.e., the inner container or the material that comes in contact with the cleaning product ingredients.)

At each renewal of DfE partnership agreements, partners must report on the status of their packaging practices in relation to each listed criterion and show progress in meeting their sustainability goals.

- Is sourced, manufactured, transported, and recycled using renewable energy;
- Optimizes the use of renewable or recycled source materials;
- Is manufactured using clean production technologies and best practices;
- Is made from materials healthful in all probable end-of-life scenarios;
- Is physically designed to optimize materials and energy; and
- Is effectively recovered and used in biological and/or industrial closed-loop cycles.

Note: Partners or candidates for partnership who have exceeded the 25% level and maximized their sustainable packaging opportunities need make no further showing.

Packaging materials may not contain heavy metals in accordance with Toxics and Packaging Clearinghouse (TPCH) model legislation. These criteria may be found at http://www.toxicsinpackaging.org/model_legislation.html. Additionally, packaging materials may not contain other ingredients of concern, including Bisphenol A (BPA) or the following phthalates: dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), butyl benzyl phthalate (BBP), di-n-pentyl phthalate (DnPP), di (2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DnOP), diisononyl phthalate (DINP), and diisodecyl phthalate (DIDP).

4.2.7 Volatile organic compounds (VOCs), hazardous air pollutants (HAPs), and Toxics Release Inventory (TRI) toxic chemicals

4.2.7.1 Volatiles Organic Compounds

In view of the contribution VOCs make to indoor air pollution and associated respiratory concerns, DfE restricts product VOC-content based on the most stringent government criteria. Thus, pending revision to the EPA Office of Air and Radiation (OAR) regulations on product VOC content (at 40 CFR 59, Subpart C), DfE will adhere to VOC restrictions as prescribed by the Ozone Transport Commission (OTC) (see federal Clean Air Act, sections 176A and 184) and the California Air Resource Board (CARB). When these criteria are not in agreement and a product may be used in an ozone-nonattainment area (as per OAR regulations at 40 CFR 50, 51 and 81), the more stringent standard will apply. (VOC criteria from OTC can be found under “Model Rule 2006 Consumer Products” at <http://www.otcair.org/interest.asp?Fview=stationary#>. VOC criteria from CARB can be found under “Regulation for Reducing VOC Emissions from Consumer Products” at <http://www.arb.ca.gov/consprod/regs/gencregs.htm>.)

4.2.7.2 Hazardous Air Pollutants

DfE does not allow products containing chemicals that are included on EPA’s list of pollutants designated as hazardous air pollutants (HAPs) or air toxics. The list of HAPs can be found at <http://www.epa.gov/ttn/atw/188polls.html>.

4.2.7.3 Toxics Release Inventory

DfE does not allow products containing chemicals included on EPA’s Toxics Release Inventory chemical list, except those that meet the DfE safer ingredient criteria. The TRI list of chemicals can be found at <http://www.epa.gov/tri/trichemicals/index.htm>.

4.2.8 Flammability

Labeled products must not exhibit the characteristic of ignitability, as defined at 40 CFR 261.21 (a)(1)), and therefore must have a flash point at or above 60°C (140°F). The flash point shall be determined by a closed-cup method, specifically, ASTM E502, or an equivalent method agreed to by EPA/DfE.

4.2.8.1 Industrial laundry detergents

Manufacturers of laundry detergents formulated for industrial applications must provide information on the product’s potential to combust spontaneously, i.e., the temperature at which they would catch fire without an outside source of ignition.

4.3 Cleaning Systems

A cleaning system, such as a laundry system, is not eligible for recognition unless every component meets the DfE Criteria. The DfE logo may be used to indicate recognition for the cleaning system, but not on individual components in the system unless they have independent, end-use applications.

4.4 Continuous Delivery Systems for Consumer Products

DfE will consider for recognition consumer products in innovative continuous delivery systems (as distinct from products poured from a bottle or manual spray pumps) that reduce the potential for inhalation exposure and meet other environmental goals. Recognition candidates must demonstrate significant innovation and environmental leadership. Product ingredients must satisfy the DfE criteria set forth in this document.

If ingredients satisfy DfE criteria, products in continuous delivery systems may be recognized if they meet the following conditions:

- 1) Propellant. The system propellant does not pose concerns for the environment and human health

(e.g., compressed air; inert gas, like nitrogen; or CO₂, if captured from combustion processes, with zero net increase in atmospheric CO₂).

2) Particle size distribution. Either a) the product contents from nozzle to the point of delivery are in a form that does not contain inhalable or respirable particles (e.g., foam); or, b) if the product contents are delivered in particle form, the distribution of particles below 10 microns (the inhalation threshold) must be less than 1 percent and below 3.5 microns (the deep-lung respirability threshold) must be at 0 percent, as demonstrated by the Malvern Mastersizers or other generally accepted method for measuring particle size of liquid sprays.

3) Packaging. a) Internal packaging. Any internal product packaging must not contain chemicals of concern per the DfE criteria; b) External packaging. The product container and other external packaging is made, to the extent feasible, of recycled materials and is itself recyclable.

4.5 Products Designed for Dermal Contact

In addition to the criteria in this standard, products whose use will involve prolonged dermal contact must comply with the supplemental requirements listed below (the DfE Ingredient Criteria at <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm> contain guidance on appropriate testing). To the extent these products fall under the jurisdiction of the Food and Drug Administration (FDA), DfE will consult with FDA prior to implementing this provision. (DfE will be guided by FDA judgments, as expressed, for example, in official monographs, on the safety of products and ingredients.)

4.5.1 Non-irritants

Only ingredients that are non-irritating to skin and eyes, as demonstrated by testing, clinical studies or consumer experience, will be acceptable. At a minimum, a product or its ingredients must not be categorized as an irritant under EPA Office of Pesticide Program regulations (i.e., must not require a precautionary statement) or GHS criteria.

4.5.2 pH

To further minimize the potential for dermal, eye or mucous membrane irritation, product pH must be greater than or equal to (\geq) 4 and less than or equal to (\leq) 9.5; products with a pH outside this range may be considered for recognition if *in vivo* testing (or scientifically valid non-animal testing) demonstrates they are non-irritating, or if they are known to be non-irritating based on their physical-chemical properties (e.g., buffering capacity).

4.5.3 Allergens and sensitizers

No ingredients classified under GHS as skin or respiratory sensitizers are permitted in labeled products. The labeling of FDA food allergens (e.g., peanut, soy, dairy) must follow the requirements in the Food Allergen Labeling and Consumer Protection Act of 2004.

4.5.4 Dermal absorption

Where an ingredient may be dermally absorbed, the applicant must provide data, for example, repeated dose toxicity testing via the dermal route of exposure, on potential effects; these data must indicate that the ingredient presents a low hazard concern.

4.5.5 Potential endocrine effects

Chemicals that are candidates for endocrine screening will be part of the review. Chemicals found to interact with or perturb the endocrine system, if associated with reproductive, developmental, carcinogenic, systemic, hormonal or other effects, will not be allowed.

4.5.6 Residuals of concern

Partnership candidates must submit to DfE data from raw material suppliers on the percentage of residuals in their products. Residuals of concern (see definition at 2.1.55 and provision at 5.13) that cannot be eliminated must be restricted to the lowest possible levels.

4.5.7 Colorants

Color additives, in any product type, must meet both FDA requirements and DfE criteria for health and environmental safety. Any candidate colorant must appear on the FDA list for use in the United States and comply with FDA regulations on appropriate conditions for use (as per 21 CFR Parts 70-82).

4.5.8 Fragrances

Fragrances must comply with the DfE Criteria for Fragrances (at <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Fragrances>); the criteria will apply to all fragrance components regardless of percentage in the fragrance.

4.5.9 Ingredients on prohibited lists

Ingredients on authoritative lists of chemicals prohibited or restricted for use in cosmetics—notably, the FDA Cosmetics list (see 21 CFR 700.11 et seq.), the European Union Cosmetic Directive (Annex II), the Health Canada “Hotlist,” and the Cosmetic Ingredient Review “Unsafe for Use” list (at <http://www.cir-safety.org>)—will not be acceptable in labeled products, as confirmed by their toxicological hazard and failure to pass the DfE safer ingredient criteria.

5 Component-Specific Requirements

5.1 Scope

The requirements of this section apply to the components of a finished cleaning product. The general requirements outlined in Section 5.2 will apply to all chemicals unless noted differently in the functional-class-specific criteria.

5.2 General Requirements

The general requirements listed in the DfE Master Criteria for Safer Chemical Ingredients (<http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Master>), as applied by experts in the DfE Program, are intended to be a minimum set of criteria all ingredients must meet to be acceptable for use in a DfE-recognized product. The subsequent sections are additional requirements or exceptions to the general requirements for specific functional-use ingredient categories.

For every chemical, ingredient data are required for each endpoint to confirm that the ingredient meets the DfE criteria. Established lists from authoritative bodies, such as the IARC and NTP carcinogen lists, may be used to screen ingredients, where available and as noted in the criteria below. When an ingredient is not found on a list, raw data for each endpoint are preferred. Appropriate analog data, applied via predictive models, may also be used to fill data gaps.

5.2.1 Supplemental requirements for components that appear on certain lists of chemicals of potential concern

If a component appears on one of the following lists of chemicals of potential concern, it will be screened as described in Section 5.2: the California Proposition 65 list, which includes substances the state lists as causing cancer, birth defects, or other reproductive harm; the list of substances prioritized for testing for

endocrine disruption by the European Commission; and the list of potential sensitizers published by the Association of Occupational and Environmental Clinics.

5.3 Surfactants

Surfactants must meet the criteria described in detail in the DfE Criteria for Surfactants at <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Surfactants>.

5.4 Direct-Release

Ingredients contained in products that are intended for use in applications that result in their immediate discharge to the environment, so that they bypass sewage treatment or septic systems, must meet the criteria in the DfE Criteria for Environmental Toxicity and Fate for Chemicals in Direct Release Products at <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Toxicity>.

5.5 Solvents

Solvents must meet the general requirements in Section 5.2 unless otherwise noted below.

5.5.1 Alcohols, esters, ethylene glycol ethers, and propylene glycol ethers

Solvents classified as alcohols, esters, ethylene glycol ethers, or propylene glycol ethers must meet the solvent criteria described in detail in the DfE Criteria for Safer Solvents in Cleaning Products(phase I): the Solvent Screen.

<http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm>

5.5.2 d-Limonene

As a solvent ingredient, d-limonene (chemical class: terpenes) may only be used in a DfE-recognized product in concentrations at which the potential oxidation products may be present at 20 millimoles per liter (mmol/L) or less (corresponding to a limonene concentration of 1.36 percent or less) in an overall formulation. Based on the potential to accelerate formation of oxidation products, d-limonene may not be used in combination with oxidizers, like H₂O₂; and based on its potential toxicity to aquatic organisms, d-limonene may not be used in direct-release products (see Section 5.4).

5.6 Fragrances

Fragrances shall be evaluated according to the requirements of the DfE Criteria for Fragrances.

(<http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm>)

5.6.1 d-Limonene

As a fragrance ingredient, d-limonene may only be used in a DfE-recognized product at concentrations up to 0.01 percent in the final cleaning product.

5.7 Builders

Builders must meet the general requirements in Section 5.2 unless otherwise noted below.

5.7.1 Chelators

Chelators must meet the criteria described in detail in the DfE Criteria for Chelating Agents general requirements in Section 5.2. In addition, DfE-recognized products must not contain inorganic phosphates that contribute to the process of eutrophication, nor NTA, a potential carcinogen. Chelators that have molecular weight (MW) above 1000 shall be evaluated under the polymer criteria.

5.7.2 Alkalinity boosters, pH adjusters & buffering agents

Alkalinity boosters, pH adjusters & buffering agents must meet the general requirements in Section 5.2. In addition, see the pH restrictions for the formulated product under Sections 4.2.2 and 5.14.2.

5.8 Polymers

Polymers must meet the general requirements in Section 5.2.

In addition, the following information is required for all polymers:

- molecular weight;
- ratio of each monomer in the polymer, if applicable;
- percent residual monomer;
- percent of polymer with a molecular weight of <1000; and
- percent of polymer with a molecular weight of <500.

Polymers must not consist of monomers known to cause occupational asthma (for example, diisocyanates are used in isocyanate-based polyurethanes).

5.9 Bacteria (Spores & Vegetative)

Bacteria (spores & vegetative) strains shall be evaluated using complete human health and environmental risk assessments. These risk assessments shall include hazard assessments and exposure to workers, users and the environment during product use and end-of-life.

5.10 Toxic Elements

DfE-recognized products must not contain toxic elements such as heavy metals. Unavoidable de minimis levels may be present, e.g., from inorganic materials mined from the earth.

5.11 Enzymes and Enzyme Stabilizers

Enzymes and enzyme stabilizers shall meet the general requirements in Section 5.2, except as defined herein. (Products that contain live microbial cultures or viable spores are addressed in separate DfE guidance.)

To help prevent inhalation of aerosolized enzymes, only liquid enzyme formulations or low-dust granulated enzyme formulations (i.e., encapsulated products with a minimum diameter of 0.15 mm) will be acceptable in labeled products. If in a dry form, in addition to using only low-dust granulated enzymes, manufacturers must exercise and be able to demonstrate best efforts to ensure a safe workplace (for example, through dust control and allergy surveillance programs and the use of appropriate personal protective equipment, as needed).

The enzymes used in cleaning products must be well characterized, and their technical names and catalytic activities must be provided to DfE. Candidate partners must also submit the genus and species of the production organisms, including appropriate taxonomic data, as needed, and documentation of appropriate quality control measures.

If present at appropriate levels, boric acid (and certain of its neutralized salts) may be used as a stabilizer in products containing DfE-acceptable protease enzymes. DfE encourages the development of safer alternative stabilizers.

5.12 Disposable Wipes

Disposable wipes must be demonstrated to be compostable or flushable as formulated.

DfE considers wipe composition and ability to decompose under mesophilic conditions (20-45°C) as key characteristics for disposable cleaning wipes when they are the intended method of application for a cleaning formulation. At a minimum, wipes must be made entirely of compostable material (ASTM D5338-98).

As an alternative to testing, companies may have their suppliers submit a certificate of analysis, showing that the wipe is made of natural, compostable materials.

To be flushable, a disposable wipe must pass through the toilet and drainline system, be transported in wastewater conveyance systems, and be compatible with wastewater treatment systems where they exist, or in some regions, discharges of untreated wastewater. An example of an acceptable test protocol is the Guidance Document for Assessing the Flushability of Nonwoven Consumer Products, published by INDA, the U.S.-based association of nonwoven fabrics industry and EDANA, the European-based international association serving the nonwovens and related industries.

5.13 Residuals

Residuals of concern must be limited to less than 0.01 percent (by weight) or 100 ppm in the formulation. For ingredients known to contain residuals of concern, DfE's goal will be to limit those residuals to the lowest practicable levels. Dilution will not be considered in calculating the percentage of residuals in concentrates. Formulators should understand that residuals may be present and should encourage chemical manufacturers to carefully monitor and control processes to limit residuals of concern. [Note: DfE is working to ascertain the extent to which the state of green chemistry can support the restrictions imposed by this section.]

5.14 Other Ingredients

The following ingredients must meet the general requirements in Section 5.2.

- Cross-linkers
- Solubility enhancers
 - Hydrotropes
 - Small amines
- Bleaching agents
- Preservatives/antioxidant
- Rheology modifiers
- Plasticizers
- Foam Boosters, defoamers and antifoamers
- Denaturants
- Absorbents and adsorbents
- Corrosion inhibitors
- Antiredispersion agent
- Dispersing agent
- Coalescing agent
- Dyes & optical brighteners

6 Use of the Mark

6.1 Terms of Use

6.1.1 The partner may use the DfE logo, shown below, on containers or container packaging of Qualifying Products or on advertising related solely to these products, provided that EPA/DfE has reviewed and approved the intended use of the logo. The partner shall not use the logo or describe EPA/DfE's recognition on any general company materials, non-Qualifying Products or associated literature, or advertising not

related to the Qualifying Products. The partner is not permitted to use the EPA official seal or logo at any time.

6.1.2 Use of the DfE logo must be accompanied by the following informational tagline, in close proximity to the logo: "Recognized for Safer Chemistry." The tagline must also include the EPA Web address, www.epa.gov/dfe, as shown below. Additionally, the partner must include in advertising of the Qualifying Products an endorsement disclaimer and various educational information for the consumer regarding the DfE partnership. The partner and EPA/DfE shall work to find an appropriate place (e.g. company Web site) connected with advertising for the Qualifying Products to include the following language along with educational information:

EPA/DfE recognition does not constitute endorsement of this product. The Design for the Environment logo signifies that the formula for this product, as «Company_Name» has represented it to the EPA, contains ingredients with more positive health and environmental characteristics than conventional cleaners. EPA/DfE relies solely on «Company_Name», its integrity and good faith, for information on the composition, ingredients, and attributes of this product. EPA/DfE has not independently identified, i.e., via chemical analysis, the ingredients in the product formula, nor evaluated any of «Company_Name»'s non-ingredient claims. EPA/DfE provides its evaluation only as to the environmental and human health characteristics of the product, based on currently available information and scientific understanding.

6.1.3 The partner and EPA/DfE acknowledge that under 5 C.F.R. §2635.702(c), EPA will not endorse the purchase or sale of commercial products and services provided by the partner. The Parties agree to ensure that promotional materials describing or resulting from this Agreement do not contain statements implying that EPA/DfE endorses the purchase or sale of commercial products. This includes statements to the public in news releases, publications, on web sites or any other media.

6.1.4 The partner shall make available to EPA/DfE for review and approval any materials, including press releases, promotional materials and advertisements that the partner develops in connection with the partnership, and especially information that describes or characterizes the DfE Safer Product Labeling Program or EPA/DfE's position on issues related to the cleaning product sector.

6.1.5 The partner must discontinue use of the DfE logo or any other form of EPA/DfE recognition, within 30 days, under the following circumstances: If the partner stops formulating the Qualifying Products using the agreed-upon ingredients; upon the termination of this Agreement; or, if so notified by EPA in writing.

6.2 Examples of Appropriate Use of the EPA/DfE Certification Mark

Example 1:



Recognized for Safer Chemistry
www.epa.gov/dfe

Example 2:



Recognized for Safer Chemistry
www.epa.gov/dfe

7 Profiler Requirements

Candidates for DfE recognition must use the services of a qualified third party profiler to prepare product recognition applications. To become a qualified third party profiler the candidate must submit a paper application to provide evidence of competency against the requirements in Sections 7.1 and 7.2, and undergo the pilot review described in Section 7.3.

7.1 Elements of Technical Competence

The profiler must have the skills, experience, and resources to perform chemical hazard assessments.

7.1.1 Staff

A profiler shall have the appropriate personnel to perform hazard assessments. Staff shall include chemists, biologists, toxicologists, or others with science/technical backgrounds.

7.1.2 Assessment and interpretation abilities

A profiler shall establish the ability to assess and interpret diverse toxicological and other health and environmental information. This shall include maintenance of appropriate staffing; a track record as a data

reviewer; experience as a standards developer or certifier to standards or criteria. The profiler shall meet the criteria of International Standards Organization (ISO) 65 to demonstrate a commitment to maintaining these capabilities.

7.1.3 Access and management of hazard information

A profiler shall establish the ability to access and manage chemical, health and environmental hazard information, including fluency with chemicals at the structural level. This shall be indicated by appropriate staffing, with chemical and information technology expertise; protocol and equipment for data searching, storage and retrieval; and relevant experience and work products.

7.1.4 Use of estimation models and software

A profiler shall demonstrate skill at using EPA and other physical-chemical and environmental estimation models and software. This must be indicated by involvement with EPA's Sustainable Futures Program; submission of Sustainable Futures Premanufacture Notices; and relevant experience and work products.

7.1.5 Secure handling of proprietary business information

A profiler shall have the appropriate systems and procedures in place to ensure the protection of all proprietary business information obtained through the review process for this program.

7.2 Elements of credibility and good standing

The profiling organization must be able to establish neutrality, trustworthiness, and reliability.

7.2.1 A profiler shall demonstrate a commitment to objectivity and due process approach by meeting the criteria of ISO 65.

7.2.3 A profiler shall demonstrate familiarity with DfE Safer Product Labeling Program review process and assessment methodology by having training and interacting with DfE and companies interested in DfE recognition.

7.2.4 A profiler shall demonstrate a track record of high performance. This shall be supported by testimonials from clients and others in a position to evaluate performance.

7.3 Pilot review requirements

7.3.1 As the final step in the process the profiler shall demonstrate competency through a review of a formulation(s) judged by DfE to be representative of those recognized by the program. DfE will review the results against the criteria in this section and determine whether the applicant has demonstrated competence.

Annex A

Partnership Agreement

**PARTNERSHIP AGREEMENT
BETWEEN
«COMPANY»
AND
U.S. ENVIRONMENTAL PROTECTION AGENCY
DESIGN FOR THE ENVIRONMENT PROGRAM**

A.1 Statement of Purpose

The purpose of this Partnership Agreement (“Agreement”) is to set forth the basis, terms, and goals of the Design for the Environment (“DfE”) voluntary partnership between «Company» (“«Company_Name»”) of «City_State_Zip_» and the U.S. Environmental Protection Agency (“EPA”). The partnership is part of the DfE safer chemical use initiative for commercial formulators. The basic goal of the initiative is to seek and promote innovative chemical products, technologies, and practices that benefit human health and the environment.

A key purpose of the partnership program is to recognize and encourage the formulation of products with environmentally preferable chemistry and collateral benefits, as defined and described in the DfE Standard for Safer Cleaning Products (the “Standard”) and the associated DfE component-class criteria. For the purpose of this Agreement, these products include the following «Company_Name» products: «Trade_Names» (the “Qualifying Products”). The partnership will strive to promote and advance the environmental, technological, and efficiency benefits of these and future Qualifying Products.

This Agreement describes in general terms how «Company_Name» formulates the Qualifying Products, their environmental and human health benefits, and how «Company_Name» and EPA/DfE will work together to continually improve the health and environmental profile of the Qualifying Products and educate the consumer on these improvements and the DfE Program.

A.2 Statement of Context and Challenge

Each year, commercial formulators use billions of pounds of chemical ingredients to make a wide variety of general purpose and specialized cleaning products. EPA is concerned about the effect certain chemicals might have on environmental quality and on the health and safety of workers and the public who use cleaning products or may come in contact with them.

EPA believes that cleaning product formulators can improve the environmental and health profile of their products by using ingredients that are inherently less toxic, less environmentally persistent, less bio-accumulative, and that degrade to substances with similar desirable characteristics when compared to ingredients in some conventional formulations. Additional benefits can be derived through environmentally oriented reformulation. Energy efficiency, resource conservation, and sound management practices offer important additional components for measurable and sustainable improvement in cleaning products and programs.

EPA believes that conventional cleaning formulations, especially those for industrial/institutional (“I/I”) use, may rely on certain ingredients whose environmental and human health profiles can be improved.

A.3 «Company_Name»'s Improved Cleaning Chemistries

In conjunction with the DfE review process, «Company_Name» has reformulated a set of cleaning products for I/I cleaning and maintenance that, according to «Company_Name», meet EPA/DfE's recommendations and offer improved health and environmental characteristics. These Qualifying Products contain no (e.g. inorganic phosphates, hazardous solvents, or environmentally harmful surfactants). Instead, they use a proprietary blend of (e.g. surfactants, solvents, pH adjustors, and other ingredients), which exhibit more positive environmental and human health characteristics than conventional cleaning formulations.

In addition, these Qualifying Products only use surfactants that biodegrade readily to non-polluting substances, which helps relieve stress on the environment, especially threats to aquatic life. By not including environmentally harmful builders or extreme pH in these formulations, the environment-friendly profile and safety characteristics of these products is further enhanced. For example, an inorganic phosphate-free formula may promote a better balance of nutrients in the environment and healthier fresh water bodies. Safer sequestrants biodegrade readily to non-hazardous compounds and protect against environmental loading of metals. Mild pH formulas help protect workers, the environment, and building infrastructure. (For more information on the attributes and benefits of these products, see Section 7.)

Please Note: EPA/DfE relies solely on «Company_Name», its integrity and good faith, for information on the composition, ingredients, and attributes of its Qualifying Products. EPA/DfE has not independently identified, i.e., via chemical analysis, the ingredients in the submitted formulas, nor evaluated any of «Company_Name»'s non-ingredient claims. EPA/DfE provides its evaluation only as to the environmental and human health characteristics of the Qualifying Products, based on currently available information and scientific understanding. «Company_Name»'s obligations under any federal, state, or local regulations governing the company or these products are in no way altered by its partnership with EPA/DfE.

A.4 «Company_Name»'s Commitment to Formulate for the Environment

As part of the «Company_Name»–EPA/DfE partnership, «Company_Name» agrees to formulate and produce the Qualifying Products using agreed upon ingredients which have a more positive health and environmental profile than conventional formulations. To preserve the non-confidential nature of this document, a generic description of the ingredients in the Qualifying Products and their key characteristics appears below.

As documentation of the Qualifying Products at the time of this Agreement, and to set a baseline for future improvements and formula changes, «Company_Name» has provided to EPA/DfE the specific and complete chemical composition for these products. This section's ingredient-by-ingredient descriptions are intended to serve as surrogates for the actual formulas. «Company_Name» reserves the right, however, to change ingredients, provided that their health/environmental profile is equal to or better than those in the current formulations and that any substitution occurs in consultation and agreement with EPA/DfE (see Section 11).

If any change is made to the agreed formulation, «Company_Name» agrees to notify EPA/DfE of the change and provide the new formulation. EPA/DfE agrees to notify «Company_Name» of the need for ingredient profiling and will make recommendations for changes to the formulation as needed in order to remain a Qualifying Product.

The following is a non-confidential representation of the ingredients in the Qualifying Products, with their key characteristic (including green chemistry status or areas identified for future improvement), as evaluated by EPA/DfE:

Ingredient
«Product_Name»
e.g. Surfactant

Key Evaluation Characteristic

*Readily biodegradable, low concerns for byproducts.
Meets DfE Standard for Surfactants.*

Solvent
Builder
Colorant

Low health and environmental concerns.
Low health and environmental concerns.
Could be improved (see sec. 5)

Adoption and use of the formulations described in this Agreement does not preclude, nor should it impede, «Company_Name» in its efforts to further improve the health and environmental profile of the Qualifying Products. In fact, a main element of the «Company_Name»–EPA/DfE partnership is to provide «Company_Name» the opportunity to work with EPA chemists, environmental scientists, and risk reduction staff in investigating materials to further improve the health and environmental profile of its Qualifying Products.

A.5 Continuous Environmental Improvement

«Company_Name» agrees to make continuous environmental improvement an important element of its research and development activities related to its Qualifying Products. In addition to the environmentally oriented formulations set forth in Section 4, «Company_Name» agrees to investigate the feasibility of making additional improvements in the environmental and health profile of the Qualifying Products. Specifically, «Company_Name» agrees to consider use of an alternative preservative and colorants, as recommended by EPA/DfE. «Company_Name» agrees to undertake this formulation review during the period of the Agreement

«Company_Name» may consult with EPA/DfE about other products and, following EPA/DfE review and assessment, may request that one or more new Qualifying Products be added to this Agreement. With EPA/DfE's approval, this Agreement may be amended as set forth in Section 11 to include new Qualifying Products.

«Company_Name» and EPA/DfE agree to discuss on a yearly basis the status of «Company_Name»'s reformulation research and continuous improvement activities related to the Qualifying Products. «Company_Name» may, at any time, request consultation and technical assistance from EPA in determining which chemical ingredients possess more positive health/environmental characteristics. «Company_Name» may use informational materials from DfE's website, for example, the *DfE Formulator Program: A Discriminating and Protective Approach to Cleaning Product Review and Recognition* (http://www.epa.gov/dfe/pubs/formulat/formulator_review1.pdf), as general guides to environmentally desirable attributes for cleaning products.

A.6 Formulator Right to Know

Cleaning product formulators have a right to know the properties and potential risks – to their employees, customers, and communities – of the chemicals they use. Manufacturers of raw materials for detergents and other cleaning products should ascertain and communicate the properties and potential toxicity of their products, especially those made and sold in large quantities.

As part of its partnership with EPA/DfE, «Company_Name» agrees to ask its raw material suppliers for test data on the chemicals they sell and that «Company_Name» uses in its products. If the raw material suppliers do not have test data on their chemicals, «Company_Name» agrees to encourage them to perform basic physico-chemical and toxicity testing. Upon request by EPA/DfE, «Company_Name» agrees to share with EPA/DfE any available chemistry or toxicity information on its ingredients that it obtains from its suppliers.

To help ensure that any new testing serves to enhance the profile and general understanding of a particular chemical, all prospective studies should be considered in the context of the guidance offered in EPA's High Production Volume Challenge Program (<http://www.epa.gov/chemrtk/volchall.htm>) and the Screening Information Data Set (SIDS) Program of the Organization for Economic Co-operation and Development (OECD) (to learn more, visit <http://www.epa.gov/oppt/chemtest/oecdids.htm> and the SIDS Test Guidelines at <http://www.epa.gov/chemrtk/sidsappb.htm>).

A.7 User Benefits

«Company_Name»'s Qualifying Products offer users the following set of benefits:

Environmental protection

The Qualifying Products are formulated with the environment and human health strongly in mind and use the following types of ingredients: biodegradable surfactants, with byproducts that are less toxic than the parent compound; solvents that are not hazardous air pollutants and pose no threat to the Earth's ozone layer; fragrances that have been screened for potential hazardous and persistent ingredients; and other components with a more positive environmental profile than in conventional cleaning products.

Worker/consumer safety

The Qualifying Products are also formulated to help ensure a safer workplace. Users of these products benefit from ingredients that include no components that pose serious hazards. This benefit is amplified for janitors, maintenance staff, housekeepers, and others who must use cleaning chemicals in confined spaces on a daily basis. Importantly, a safer health profile especially benefits children, who spend a large part of their day in indoor environments and can be particularly sensitive to the chemicals in some cleaning products. Also, the mild pH, low volatility, and low potential to catch fire enhance the safety profile of these products.

Resource conservation

The Qualifying Products also have certain attributes that may significantly reduce wear and tear on substrates, fabrics, and other surfaces with which the products come in contact, thereby extending their usable life.

Customer education

«Company_Name» acts as a product steward by providing its customers information on environmental and worker safety matters and trains its sales force on the benefits of formulations with improved environmental and health characteristics.

«Company_Name» agrees to inform customers of Qualifying Products about the «Company_Name»-EPA/DfE partnership, the meaning of the DfE logo, and the DfE Program's role in helping to protect human health and the environment. «Company_Name» agrees to make available to its customers an EPA/DfE contact to whom they may direct questions or comments on the partnership.

A.8 EPA Recognition and Support

«Company_Name» may use the Design for the Environment (DfE) logo, shown on Attachment A to this Agreement, on containers or container packaging of Qualifying Products or on advertising related solely to these products, provided that EPA/DfE has reviewed and approved the intended use of the logo. «Company_Name» agrees to not use the logo or describe EPA/DfE's recognition on any general «Company_Name» materials, non-Qualifying Products or associated literature, or advertising not related to the Qualifying Products. «Company_Name» is not permitted to use the EPA official seal or logo at any time.

Use of the DfE logo must be accompanied by the following informational tagline, in close proximity to the logo: "Recognized for Safer Chemistry." The tagline should also include the EPA web address, www.epa.gov/dfe, as shown on Attachment A. Additionally, «Company_Name» agrees to include in advertising of the Qualifying Products an endorsement disclaimer and various educational information for the consumer regarding the DfE partnership. «Company_Name» and EPA/DfE agree to work to find an appropriate place (e.g. company website) connected with advertising for the Qualifying Products to include the following language along with educational information:

EPA/DfE recognition does not constitute endorsement of this product. The Design for the Environment logo signifies that the formula for this product, as «Company_Name» has represented it to the EPA, contains ingredients with more positive health and environ-

mental characteristics than conventional cleaners. EPA/DfE relies solely on «Company_Name», its integrity and good faith, for information on the composition, ingredients, and attributes of this product. EPA/DfE has not independently identified, i.e., via chemical analysis, the ingredients in the product formula, nor evaluated any of «Company_Name»'s non-ingredient claims. EPA/DfE provides its evaluation only as to the environmental and human health characteristics of the product, based on currently available information and scientific understanding.

The Parties acknowledge that under 5 C.F.R. §2635.702(c), EPA may not endorse the purchase or sale of commercial products and services provided by «Company_Name». The Parties agree to ensure that promotional materials describing or resulting from this Agreement do not contain statements implying that EPA/DfE endorses the purchase or sale of commercial products. This includes statements to the public in news releases, publications, on web sites or any other media.

«Company_Name» agrees to make available to EPA/DfE for review and approval any materials, including press releases, promotional materials and advertisements that «Company_Name» develops in connection with the partnership, and especially information that describes or characterizes the DfE Formulator Program or EPA/DfE's position on issues related to the cleaning product sector.

«Company_Name» agrees to discontinue use of the DfE logo or any other form of EPA/DfE recognition, within 30 days, under the following circumstances: If «Company_Name» stops formulating the Qualifying Products using the agreed upon ingredients; upon the termination of this Agreement; or, if so notified by EPA in writing.

A.9 Limitations

All commitments made by EPA in this Agreement are subject to the availability of appropriated funds and budget priorities. Nothing in this Agreement, in and of itself, obligates EPA to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or incur other financial obligations. This Agreement does not exempt «Company_Name» or any other organization from EPA policies for competition for financial assistance agreements or procurement contracts. «Company_Name» agrees not to submit a claim for compensation for services rendered to EPA in connection with any activities it carries out in furtherance of this Agreement. Any endeavor involving reimbursement or contribution of funds between the parties to this Agreement will be handled in accordance with applicable laws, regulations, and procedures, and will be subject to separate agreements.

This Agreement does not create any right or benefit, substantive or procedural, enforceable by law or equity against «Company_Name» or EPA/DfE, their officers or employees, or any other person. This Agreement does not direct or apply to any persons outside «Company_Name» or EPA.

A.10 Measures of Success

On an annual basis, «Company_Name» agrees to provide to EPA/DfE its best estimate of the production volume of the Qualifying Products (if possible, both in aggregate pounds or gallons and broken out by ingredient class).

At EPA's request, «Company_Name» agrees to make available to EPA/DfE, on a confidential basis, formulation bills of materials that confirm that the Qualifying Products contain the ingredients agreed to in this Agreement or have been modified in accordance with its terms.

«Company_Name» agrees to make reasonable attempts to monitor the cleaning product market and agrees to inform EPA/DfE about the Qualifying Products' influence on the market, including growth in sales and number of new customers, as well as the perceived value in DfE recognition. «Company_Name» agrees to report on customer acceptance of and satisfaction with these products when this information is available.

As discussed in Section 5, «Company_Name» agrees to furnish periodic updates to EPA on the continuous improvement component of its research and development activities and on its ongoing efforts to improve the health/environmental profile of the Qualifying Products. As a condition of partnership, «Company_Name» has demonstrated to EPA/DfE the performance of its Qualifying Products according to the guidelines provided by DfE (http://www.epa.gov/dfe/pubs/formulat/formulator_review1.pdf). «Company_Name» agrees to also share with EPA/DfE the results of any additional performance testing or verification when that information becomes available.

A.11 Confidentiality

In matters relating to this DfE partnership and Agreement, EPA agrees to handle all information claimed by «Company_Name» as confidential business information in accordance with EPA confidentiality procedures (see 40 CFR part 2, subpart B). EPA and «Company_Name» agree that information supplied to EPA by «Company_Name» on the formulas of any «Company_Name» products is covered by the foregoing sentence.

EPA/DfE agrees to only use the information provided by «Company_Name» for purposes related to the «Company_Name»-EPA/DfE partnership and disclose the information only to EPA employees and EPA contractors cleared for confidential information with a specific need to know.

A.12 Amendments to the Agreement

As discussed in the Continuous Environmental Improvement section, «Company_Name» may request that EPA/DfE add new Qualifying Products to this Agreement when reformulated. If EPA agrees to the addition, «Company_Name» may amend the Agreement by submitting a letter that addresses the essential elements from Sections 3, 4, 5 and 7 of the current Agreement. «Company_Name» and EPA/DfE agree to collaborate in developing the specific language for the amendment, which must be signed by an appropriate official for both parties. All other provisions of the Agreement shall be incorporated by reference.

A.13 Private Label, Licensee, and Toll Manufacture Products

«Company_Name» acknowledges and agrees to the following roles, limitations, and responsibilities when third parties are involved in the manufacture of DfE-recognized products.

A private label product may carry the DfE logo provided that its contents are either identical to those in a specified DfE-recognized product, or very similar, and the ingredients that are different have been approved in the Partnership Agreement. A licensee or toll manufacture product may carry the DfE logo provided that its contents are identical to those in a specified DfE-recognized product.

Before manufacture of any private label product that will carry DfE recognition, «Company_Name» must inform and receive permission from DfE, indicating the name of the private label product, the label owner, and the specific DfE-recognized product to which it is identical or on which it is based. Before manufacture of any licensee or toll manufacture product, «Company_Name» must inform and receive permission from DfE, indicating the name of the licensee or toll manufacturer and of the specific DfE-recognized product to which the licensee or toll manufacture product is identical. To assure quality, the licensee or toll manufacture product must be manufactured under an agreement between «Company_Name» and the licensee or toll manufacturer and the agreement must be available to DfE on request.

«Company_Name» agrees to ensure that its private label, licensee and toll manufacture products comply with the audit provisions in Section 14.

A.14 Partnership Surveillance and Audits

To ensure that the contents of recognized products are as represented to the Agency under this agreement and that all other aspects of the «Company_Name»-DfE partnership comport with the DfE Standard

and criteria documents, “Company_Name» agrees to participate in DfE’s surveillance and auditing program. The program will consist primarily of annual desk audits and triennial on-site audits, as described in the DfE Standard, Section 3.6 and Annex B.

“Company_Name» will make its manufacturing facilities and recognized-product-related records available to DfE-authorized third-party verifiers. On an annual basis, “Company_Name» agrees to submit to the third-party verifier desk audit materials as specified in the DfE Standard, Annex B.1. These materials will include a list of ingredients for each recognized product and a statement that the ingredients and all claims made regarding the Agency’s recognition (e.g. use of the DfE logo) comport with this agreement.

Approximately every three years, “Company_Name» will allow a third-party verifier to visit its manufacturing facility and conduct an audit, which will include the elements listed the in the DfE Standard, Annex B.2. The audit will focus on the manufacturing process and the procedures in place to ensure that recognized products comport with this agreement.

If the audit reveals items of noncompliance, “Company_Name» will promptly correct the noncompliance. “Company_Name» shall submit to the external verifier and to DfE, in writing and within 30 days of receiving written notice of noncompliance, the following: a root-cause analysis, an explanation of corrective action, and a preventive action plan. In collaboration with DfE, the external verifier shall confirm that “Company_Name» has taken the remedial action necessary to assure DfE of “Company_Name»’s ability to satisfy the terms of this agreement.

Unaddressed or egregious noncompliance may serve as grounds for terminating the partnership. In any case of serious noncompliance, “Company_Name» may be asked to do the following: immediately cease use of the DfE logo; estimate the quantities of currently labeled product; and confirm the cessation and estimate in writing. Procedures for handling existing stocks of products and labels will be determined on a case-by-case basis.

A.15 Ingredient Communication

To enhance public awareness of the safer ingredients in DfE-labeled cleaning products and in the spirit of more complete communications on chemicals in common use, “Company_Name” agrees to disclose the contents of their DfE-labeled products as described herein and in the DfE Standard, Section 3.8.

“Company_Name” must disclose all intentionally added ingredients in their DfE-labeled products, except for “incidental ingredients,” that is, ingredients present at insignificant levels that have no technical or functional effect (e.g., reagents, processing aids, and impurities, as defined in 21 §701.3(l)).

“Company_Name” agrees to disclose its ingredients in one of the following locations: on the product label; on their Web site; at a toll-free number; or, on another media approved by DfE. If disclosure does not occur on the product label, “Company_Name” must provide the location of the ingredients on the label, e.g., the Web site address or toll-free number.

“Company_Name” must use the Chemical Abstract Service (CAS) number, if available and not trade secret information (as defined in the Uniform Trade Secrets Act), and one or more of the following nomenclature systems to describe their ingredients: CAS name; Consumer Specialty Products Association (CSPA) Consumer Products Ingredient Dictionary name; International Nomenclature of Cosmetic Ingredients (INCI) name; or, International Union of Pure and Applied Chemistry (IUPAC) name. Where needed to protect trade secret information, “Company_Name” may, at a minimum, use a chemical-descriptive name, for example, the EPA Premanufacture Notice generic name or the CSPA Dictionary name, in lieu of the specific chemical name; however, the name must be as specific as possible without revealing trade secret information.

“Company_Name” must list dyes, colorants, and preservatives by a chemical-descriptive name. “Company_Name” may list scent ingredients as “Fragrance” on the label, but must also indicate where detailed information can be found; for example, the Web site list, or subset of the list, of fragrance materials au-

thored by the International Fragrance Association (IFRA) and available on IFRA's Web site (<http://www.ifraorg.org/>). Alternatively, "Company_Name" may state on its Web site the ingredients in the fragrance or the palette of fragrance materials used in its products, and may also include the ingredients not used in the fragrance.

"Company_Name" must use the following order in listing ingredients: for those present at concentrations over 1.0 percent (measured on a weight-weight percentage basis), ingredients must be listed in descending order, with the ingredient at the highest percentage in formula listed first; for those present at or below 1.0 percent, ingredients may be listed in any order.

A.16 Packaging

In accordance with Section 4.2.6 of the Standard, "Company_Name" agrees that, with respect to the inner container (i.e., the packaging material that comes into contact with its labeled product ingredients), it has achieved at least at a 25 percent level in one of the six sustainability criteria listed below, developed by the Sustainable Packaging Coalition (<http://www.sustainablepackaging.org>). "Company_Name" further agrees that, if not already at a full performance level, it will improve the packaging profile of its labeled products during the partnership and that at each partnership renewal it will report on the status of its packaging practices in relation to the listed criteria and show progress in meeting its sustainability goals.

- Is sourced, manufactured, transported, and recycled using renewable energy;
- Optimizes the use of renewable or recycled source materials;
- Is manufactured using clean production technologies and best practices;
- Is made from materials healthful in all probable end-of-life scenarios;
- Is physically designed to optimize materials and energy; and
- Is effectively recovered and used in biological and/or industrial closed-loop cycles.

In addition, "Company_Partner" agrees that its packaging materials will not contain toxic elements (as per Section 5.10 of the Standard), including heavy metals, as described in the Toxics and Packaging Clearinghouse model legislation (at www.toxicsinpackaging.org/model_legislation.html). "Company_Partner" will also ensure that the following ingredients of concern are not used in its packaging: Bisphenol A (BPA) or the following phthalates: dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), butyl benzyl phthalate (BBP), di-n-pentyl phthalate (DnPP), di (2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DnOP), diisononyl phthalate (DINP), and diisodecyl phthalate (DIDP).

A.17 Termination or Renewal of the Agreement

Either party may, upon written notification, terminate this Agreement. In any event, the terms and provisions in the Agreement will sunset three years from the date of signature, unless the parties renegotiate and renew a Partnership Agreement prior to the expiration date.

We agree to these terms and provisions:

For «Company»

For the U.S. Environmental Protection Agency

Signatory
Title

Robert E. Lee II
Director, Economics, Exposure, and
Technology Division

Date _____

Date _____

Annex B

Elements of Desk Audits and On-Site Audits

B.1 Desk Audits

DfE partners will submit to the third-party verifier the following items, which are drawn from elements of the Partnership Agreement and DfE Criteria:

- List of all ingredients for each recognized product;
- Statement that the ingredients have not changed since they were provided to DfE and referenced in the Partnership Agreement or in a DfE-approved amendment to the agreement;
- Example of all product labels showing use of the DfE logo or mention of DfE recognition;
- Example of any product or company literature that use the DfE logo or mention DfE recognition;
- Any private or licensed product labels and literature that bear the DfE logo;
- Summary of continuous improvement efforts as required by the Partnership Agreement; and
- Documentation of education offered to end user.

B.2 On-Site Audits

The third-party verifier will seek the following information, based on the terms of the Partnership Agreement and DfE Criteria, at subject facilities:

- Verification that qualifying products are being manufactured using accepted ingredients and suppliers and at proper use levels. Authorized formula will be compared to manufactured product through review of production records, batch tickets, bills of lading, certificates of analysis and any other documentation necessary;
- Verification that any private label and licensed products packaged on-site are identical in formulation to the original recognized product (i.e., no dilution, concentration, no added dyes or fragrances);
- Review customer complaint file;
- Verification of end-user education;
- Review documentation of training offered to end users;
- Confirm labeling requirements including safety matters, DfE logo requirements (use of the Mark) and verify no logo or mention of the DfE program is found on non-qualifying products;
- Confirmation of appropriate product packaging;
- Review of Good Manufacturing Practices (i.e., manufacturing and packaging operations conducted within the scope of an effective quality system (e.g. ISO 9001) and in accordance with defined quality procedures appropriate for the manufacture of cleaning products). For this component the audit may include:
 - Production walk-through;
 - Review of practices for minimizing contamination of the Product during measuring, blending, packaging, and transport;
 - Verification that bulk product containers, transfer equipment, and holding vessels for Certified Product are maintained in good repair;
 - Review of records for cleaning, maintenance, and calibration of manufacturing equipment; and
 - Review of supplier qualification records (including test data) for raw materials, packaging, and ingredients.